

REMARKS

The present communication is responsive to the Office Action mailed September 15, 2009. A one-month extension of time extending the period of reply from December 15, 2010 up to and including January 15, 2010 is submitted herewith.

Claims 1-8, 10-20 and 22 were rejected in the Action. Claims 1, 14 and 22 are amended herein. No claims are added and claim 13 has been cancelled herein. Therefore, claims 1-8, 10-12, 14-20 and 22 are now pending in the Action. Applicants set forth remarks relating to the Action below.

In the Action, the Examiner objected to the drawings stating that according to the claimed embodiment, there is only one way for the tool to engage the baseplates and that it is understood the claimed embodiment is Figs. 71-82. Further, the Examiner rejected claims 13-15 and 18-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the limitation that the tool can be positioned in a plurality of ways or on any surface of the baseplate angled surfaces is not supported by the disclosure. Further, the Examiner asserted that in Figs. 71-82, the tool is only shown engaging the baseplates in one orientation.

Applicants respectfully traverse the objection to the drawings and the 35 U.S.C. § 112, first paragraph rejection of the claims. There are several paragraphs in the specification that describe in detail that the angled distal surface of the manipulation tool is engageable with the angled perimeter of at least one of the baseplates in a plurality of ways, each of the plurality of ways establishing a respective desired surgical approach angle for manipulating the intervertebral spacer device. For instance, paragraph [00153] of the present application states the following:

Also preferably, in order to provide for a holding of the static trial 100,1000 or disc 160 for two additional (here, anteriolateral) insertion approaches, each static trial 100,1000 or disc 160 also includes two additional holes 122a,1220a,182a and 122c,1220c,182c, one (e.g., 122a,1220a,182a) spaced apart from one of the anteriolaterally facing flat surfaces (e.g., 120a,1200a,180a), and the other (e.g., 122c,1220c,182c) spaced apart from the other of the anteriolaterally facing flat surfaces (e.g., 120c,1200c,180c). Accordingly, operation of the inserter/impactor 400,4000 can fit the holding pin 408,4080 into either of these two additional holes 122a,1220a,182a or 122c,1220c,182c, and hold the associated anteriolaterally facing flat surface (the one associated with the hole into which the pin 408,4080 is fit) of the static trial 100,1000 or disc 160 against the flat surface of the inserter/impactor 400,4000 opposite the pin 408,4080. For example, in a first anteriolateral approach for the trial 100,1000 (as shown in Fig. 63 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d not confronted, 120b,1200b and 120e,1200e facing 420a (or 4200a and 4200d), and 120c,1200c and 120f,1200f facing 420b (or 4200b and 4200e), and a first anteriolateral approach for the disc 160 (as shown in Fig. 69 as an example of the how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d not confronted, 180b and 180e facing 420a (or 4200a and 4200d), and 180c and 180f facing 420b (or 4200b and 4200e). And, for example, in a second anteriolateral approach for the trial 100 (as shown in Fig. 64 as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420b (or 4200b and 4200e), 120b,1200b and 120e,1200e facing 420c (or 4200c and 4200f), and 120c,1200c and 120f,1200f not confronted, and a second anteriolateral approach for the disc 160 (as shown in Fig. 70 as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420b (or 4200b and 4200e), 180b and 180e facing 420c (or 4200c and 4200f), and 180c and 180f not confronted.

The above reproduced paragraph clearly discloses that surfaces 4200a-f of inserter/impactor 4000 (shown in Figs. 71-82) are configured to engage corresponding surfaces 180a-f on disc 160. Further, the angled distal surface of inserter/impactor 4000 (i.e. the manipulation tool) is engageable with the angled perimeter of at least one of the baseplates (of disc 160) in a plurality of ways, each of the

plurality of ways establishing a respective desired surgical approach angle for manipulating the intervertebral spacer device (i.e. anteriolateral approaches, directly lateral approaches, posteriolateral approaches as described in paragraph [00153] reproduced above). These surgical approach angles are clearly shown in Figs. 59-70 and one of ordinary skill in the art reading the disclosure of paragraph [00153] of the present application, for example, would understand how manipulation tool 4000 engages disc 160 in a plurality of ways to establish a respective desired surgical approach angle for manipulating the intervertebral spacer device. In light of the foregoing, Applicants respectfully request the current objection to the drawings and § 112 first paragraph claim rejections be withdrawn.

Further in the Action, the Examiner rejected claims 1-8, and 10-22 (note that claim 21 was previously cancelled) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,117,637 to Gill *et al.* ("Gill") in view of WO 01/62191 to McGahan *et al.* ("McGahan") and U.S. Pat. No. 6,821,298 to Jackson ("Jackson"). The Examiner asserted that Fig. 1a of Gill discloses an intervertebral spacer device 20 having first and second baseplates 22, 24 that can articulate relative to one another. As the Examiner admits in the Action, the baseplates of Gill do not have an angled perimeter. Further, the Examiner asserted that Fig. 14a of Gill discloses a manipulation tool 70 having a correspondingly distal surface 76 that when engaged with the perimeter of the baseplates, rotation of the baseplates relative to the corresponding distal surface of the manipulation tool is prevented by interference between the perimeter of the baseplates and the corresponding distal surface of the manipulation tool. As described in the specification of Gill:

Prosthesis-engaging portion 76 of insertion tool 70 is also capable of retaining prosthesis 20 in

engagement with prosthesis-engaging portion 76. The illustrated embodiment of prosthesis-engaging portion 76 also includes a pair of clips 82 on both sides of prosthesis-engaging portion 76. Clips 82 are designed to hold the embodiments of ball component 22 and trough component 24 that include indentations 40 and 62, respectively. Each clip 82 is attached to prosthesis engaging portion 76, and includes two clip fingers 84 each having a thickened portion 86 for insertion into indentations 40 of ball component 22 and indentations 62 of trough component 24. In an alternative embodiment of insertion tool 70 (FIGS. 15a-15b), prosthesis-engaging portion 76 is provided with apertures 80, and a pair of cam screws 90 which extend through one aperture 80 on each side of separator flange 79. Ball component 22 and trough component 24, in the embodiment in which they include bone screw apertures 36 and 58, respectively, are engaged to prosthesis engaging surface 78 so that apertures 36 and 58 communicate with apertures 80 of prosthesis engaging portion 76. Cam screws 90 are then inserted into one of apertures 36 and one of apertures 58 to lock ball component 22 and trough component 24 to prosthesis engagement surface 76.

See col.7, ll.30-53.

There are thus additional structures on the perimeter of baseplates 22, 24 that correspond to surface 76 of insertion tool 70 of Gill to prevent the rotation of baseplates 22, 24 relative to tool 70 other than surface 76 by itself. As mentioned in the reproduced paragraph above, in one embodiment, two clip fingers 84 engage indentations 40 of baseplate 22 and indentations 62 of baseplate 24 to prevent the rotation of baseplates 22, 24 relative to tool 70 and should thus be considered part of the distal end of tool 70. Further, in another embodiment, a pair of cam screws 90 extend through apertures 80 in tool 70. These cam screws 90 are inserted into one of apertures 36 and 58 located in flanged 34 and 56 in baseplates 22, 24 respectively to lock the baseplates to engagement surface 76 of tool 70, thus preventing the rotation of baseplates 22, 24 relative to tool 70. Here, flanges 34 and 56 should be considered part of the perimeter of the baseplates

22, 24. In reference to both of these aforementioned embodiments, Gill only teaches one way or surgical approach angle that the distal surface of manipulation tool 70 is engageable with the perimeter of at least one of baseplates 22, 24.

The Examiner references McGahan for the teaching of a manipulation tool having an angled distal end that corresponds to an angled perimeter of an implant. There is no reason for one of ordinary skill in the art to incorporate the teachings of McGahan such that insertion tool 70 can engage baseplates 22, 24 in a plurality of ways, each of the plurality of ways establishing a respective desired surgical approach angle for manipulating baseplates 22, 24. If one of ordinary skill in the art were to do so, the manipulation tool of Gill could not engage the baseplates to establish other ways or surgical approach angles between the distal surface of the manipulation tool and the perimeter of at least one of baseplates because the baseplates of Gill do not have the additional structure needed to allow this to occur. Other indentations 40 and 62 are not present on the perimeter of baseplates 22 and 24. Further, flange 34 of baseplate 22 and flange 56 of baseplate 24 do not extend around the perimeter of baseplates 22, 24 so that surface 76 of tool 70 can engage baseplates 22, 24 in other ways or surgical approach angles. Therefore, one of ordinary skill in the art would not combine Gill with McGahan in the manner outlined by the Examiner in the Action to arrive at the claimed invention. Also, Jackson cannot be used to cure the deficiencies of Gill and McGahan. In light of the foregoing, amended independent claims 1 and 22 are unobvious over Gill in view of McGahan and Jackson and are in condition for allowance. Claims 2-8, 10-12, and 14-20 depending from claim 1 are also

unobvious, *inter alia*, their dependence from an allowable base claim.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 15, 2010

Respectfully submitted,
Electronic signature: /William
A. Di Bianca/
William A. Di Bianca
Registration No.: 58,653
LERNER, DAVID, LITTENBERG,
KRUHMOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

1077833_1.DOC